K082513

OCT 22 2008

OneTouch® Vita™ Blood Glucose Monitoring System

510(k) Summary

Sponsor	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035 U.S.A.
Correspondent	Primary 510(k) Contact (submitter): Oyinkan Donaldson LifeScan Scotland Ltd. Beechwood Park North Inverness, IV2 3ED United Kingdom Phone: 011-44-1463-721259 e-mail: odonalds@its.jnj.com Secondary 510(k) Contact: Mary Ellen Holden LifeScan Inc. 1000 Gibraltar Drive Milpitas, CA 95035 U.S.A. Phone: 408 942 3589 e-mail: mholden@lfsus.jnj.com
Device Name and Classification	OneTouch® Vita™ Blood Glucose Monitoring System Common name: Glucose test system Classification: (1) OneTouch® Vita™ Blood Glucose Meters and OneTouch® Vita ™ Test Strips are Class II devices (21 CFR § 862.1345) (2) OneTouch® Vita™ Control Solutions are a Class I device (21 CFR § 862.1660) (3) OneTouch® Lancing Device with OneTouch® AST ClearCap™, OneTouch® UltraSoft® Adjustable Blood Sampler with OneTouch® UltraClear® Cap and OneTouch® UltraSoft® Sterile Lancets are Class I (exempt) devices (21 CFR § 878.4800)

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System Description

The OneTouch® Vita™ Blood Glucose Monitoring System consists of the OneTouch® Vita™ Meter; OneTouch® Vita™ Test Strips (provided separately); OneTouch® Vita™ Control Solution and OneTouch® Vita™ High Control Solution (provided separately); either the OneTouch® UltraSoft® Adjustable Blood Sampler with OneTouch® UltraClear® Cap or the OneTouch® Lancing Device with OneTouch® AST ClearCap; and OneTouch® UltraSoft Sterile Lancets.

The OneTouch® Vita™ meter is a modification of the OneTouch® Select™ and OneTouch® Ultra®2 meters. The OneTouch® Vita™ test strip is a modification of the OneTouch® Ultra® test strip (component of the OneTouch® Ultra®2 Blood Glucose Monitoring System).

There are no changes to other system testing components compared to the predicate devices.

Predicate Devices - OneTouch® Select™ Blood Glucose Monitoring System (K072543, cleared 4th Oct 2007)
- OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529, cleared 17 Jan 2006)

Intended Use

The OneTouch® Vita™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® Vita™ System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and/or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The OneTouch® Vita™ Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm or palm.

Comparison to Predicate Devices

The device modifications encompass:

- Meter – ergonomic/physical design and software/firmware changes including removal of user coding step
- Test Strip – changes to electrode layout and cosmetic appearance

The OneTouch® Vita™ Blood Glucose Monitoring System has the same intended use, material composition and operating principle as the predicate devices.

Technological Characteristics

The OneTouch® Vita™ Blood Glucose Monitoring System has the same fundamental scientific technology as the OneTouch® Select™ Blood Glucose Monitoring System and OneTouch® Ultra®2 Blood Glucose Monitoring System predicate devices.

Summary of Performance Characteristics

The OneTouch® Vita™ Blood Glucose Monitoring System has the same performance characteristics as the OneTouch® Select™ Blood Glucose Monitoring System and OneTouch® Ultra®2 Blood Glucose Monitoring System predicate devices.

A comparison of system accuracy performance demonstrated that the OneTouch® Vita™ Blood Glucose Monitoring System is substantially equivalent to the currently marketed OneTouch® Select™ and OneTouch® Ultra®2 Blood Glucose Monitoring Systems.

Design Verification testing (including software verification and validation testing) confirmed that the performance, safety, and effectiveness of the OneTouch® Vita™ Blood Glucose Monitoring System is equivalent to that of the predicate devices.

The modified blood glucose monitoring system (meter and test strip) was tested in accordance with ISO 15197:2003(E). Analytical performance testing included system accuracy, repeatability and intermediate precision testing. A user performance evaluation assessed usability of the device (human factors) in the hands of intended users and validated comprehension of the proposed product labeling.

Conclusion

The OneTouch® Vita™ Blood Glucose Monitoring System is substantially equivalent to the OneTouch® Select™ Blood Glucose Monitoring System and OneTouch® Ultra®2 Blood Glucose Monitoring System predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 06 2008

LifeScan Inc.
c/o Mrs. Oyinkan Donaldson
1000 Gibraltar Dr.
Milpitas, CA 95035

Re: k082513
Trade Name: OneTouch Vita Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: September 18, 2008
Received: September 22, 2008

Dear Mrs. Donaldson:

This letter corrects our substantially equivalent letter of October 22, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082513

Device Name: OneTouch® Vita™ Blood Glucose Monitoring System

Indications For Use:

The OneTouch® Vita™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch® Vita™ System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® Vita™ Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm or palm.

Prescription Use ____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)